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(54) STEERABLE CATHETER

STEUERBARER KATHETER

CATHETER ORIENTABLE

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(73) Proprietor:
CATHETER IMAGING SYSTEMS
Atlanta, GA 30318 (US)

(72) Inventors:
- **SNOKE, Phillip, Jack**
  Atlanta, GA 30327 (US)
- **ROWLEY, David, Scott**
  Smyrna, GA 30082 (US)
- **LINCOLN, David, George**
  Smyrna, GA 30080 (US)
- **CHARLES, Kirk, William**
  Austell, GA 30001 (US)

(74) Representative:
Lieck, Hans-Peter, Dipl.-Ing.
Lieck & Partner
Widenmayerstrasse 36
80538 München (DE)

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Description

Field Of Invention

This invention relates to medical catheters, and more particularly to steerable catheters for inserting into body vessels or cavities.

Background Of The Invention

Various commercially available catheters and endoscopes exist for introducing into the body vessels and cavities a variety of surgical tools, fluids, and other materials, such as radiographic contrast materials, angioplasty balloons, fiberoptic scopes, laser lights, and cutting instruments. Also, various techniques and systems have been developed for guiding or steering the catheters in the body vessels and cavities for use of these tools, fluids, and other materials.

Examples of such guiding or steering techniques and systems for catheters may be seen in U.S. Patent No. 4,983,165 to Loiterman entitled "*Guidance System For Vascular Catheter Or The Like*," U.S. Patent No. 4,776,844 to Ueda entitled "*Medical Tube*," U.S. Patent No. 4,934,340 to Ebling et al. entitled "*Device For Guiding Medical Catheters and Scopes*," U.S. Patent No. 4,930,521 to Metzger et al. entitled "*Variable Stiffness Esophageal Catheter*," U.S. Patent No. 3,470 to Barchilon entitled "*Dirigible Catheter*," U.S. Patent No. 3,605,725 to Bentov entitled "*Controlled Motion Devices*," and the Patent Cooperation Treaty ("PCT") Patent Application No. PCTWO88/00810 of Tenerz et al. entitled "*Guide For Mechanical Guiding Of A Catheter In Connection With Cardio And Vessel Examination*." These catheters, however, failed to give the physician or other operator sufficient control of the distal end of the catheter and made it difficult to manipulate the distal end for specific isolation on particular sections of the body vessel or cavity.

Some steerable catheters or systems have been made to try to give the physician control of the use of the catheter during surgical procedures wherein fluids and the various tools are needed for the operation by providing a flexible tube for controlling the direction of movement of the distal end of the catheter. Examples of these other attempts may be seen in the PCT Patent Application No. PCTWO91/11213 of Lundquist et al. entitled "*Catheter Steering Mechanism*," European *Patent Application* No. 370,158 of Martin entitled "*Catheter For Prolonged Access*," and U.S. Patent No. 4,737,142 to Heckele entitled "*Instrument For Examination And Treatment Of Bodily Passages*." These devices, however, still failed to provide the control and manipulation of the catheter needed for use with the surgical tools and fluids required for an operation.

Other attempts to control and manipulate the catheter, such as seen in U.S. Patent 4,986,258 by Cho et al. entitled "*Endoscope With Tapered Shaft*" upon which the preamble of claim 1 is based and European Patent Office Published Application 0-489-937-A1 by Schmitt et al. entitled "*Medical Instrument*", fail to provide adequate control and manipulation while also providing adequate access to a lumen of the catheter during the surgical procedures or the like.

Therefore, there is still a need for a steerable catheter that provides the control and manipulation of the catheter for simultaneous use with the surgical tools, such as fiberoptic scopes or the like, and fluids needed for medical operations to thereby allow the physician to positionally locate and isolate problem areas within the body vessel or cavity.

Summary Of The Invention

It is therefore an object of the present invention to provide a catheter having improved steering.

It is also an object of the present invention to provide a catheter that allows the physician or operator to have more control over the distal end therein and provides feedback to the physician of the angular attitude of the distal end.

It is another object of the present invention to provide a catheter having a housing of such a size as to be readily held in the hand of the user for the physician or operator to control the steering of the catheter while simultaneously providing access to the lumen within the catheter for various surgical tools or fluids.

It is a further object of the present invention to provide a catheter having a fiberoptic scope sheath adapted to engage the housing of the catheter for inserting a fiberoptic scope into a lumen of the catheter.

These and other objects, features, and advantages of the present invention are provided in a catheter having more controlled movement in the distal end and having feedback on this movement to the catheter user the details of which are disclosed in the detailed description and the enclosed drawings.

In accordance with the present invention, a steerable catheter is provided for use in body vessels or cavities. The steerable catheter comprises a housing having upper and lower surfaces and being of such a size as to be readily held in the hand of the user. The catheter also has elongate tube means having a proximal end connected to the housing and extending outwardly therefrom and being formed of material of such a stiffness so as to maintain the elongate tube means in a substantially straight condition in the absence of an external force applied thereto. A distal end portion of the elongate tube means is flexible. Guide wires are connected to the housing by the proximal ends thereof and extend outwardly therefrom through the elongate tube means. The distal ends of the guide wires are connected to the flexible distal end portion of the elongate tube means. Guide wire control means is carried by the housing and cooperates with the proximal end portions of the guide wires for controlling the angular attitude of the flexible

distal end portion of the elongate tube means. The guide wires and control means cooperate so as to limit the angular attitude of the flexible distal end portion of the elongate tube means to angular adjustments in a common plane extending generally parallel to the upper surface of the housing and wherein the angular adjustment of the flexible distal end portion of the elongate tube means in all other planes is obtained by rotation of the user's hand, so that more control of the attitude of the flexible distal end portion of the elongate tube means is obtained during use of the catheter.

The housing includes recessed side peripheries for increased handling and control of said housing. The guide wire control means are carried by said housing within said recessed side peripheries for increasing the ease of control of said distal end portion when said housing is held in the hand of a user thereof.

A pair of lumen extend longitudinally from the distal end of the elongate tube means and into the housing. The housing has a pair of access ports positioned in the upper surface of the housing which provide access to the pair of lumen preferably through a piping connector. A fiberoptic sheath is adapted to be attached to the access port of the housing for inserting a fiberoptic scope or the like through one of the access ports and into one of the lumen. A proximal tube is also provided which extends through the housing and preferably outwardly from a proximal end of the housing.

Brief Description Of The Drawings

FIG. 1 is an environmental view of the steerable catheter being held by the hand of the catheter operator while simultaneously having a fiberoptic scope inserted into an access port in the housing of the catheter according to a preferred embodiment of the present invention.

FIG. 2 is a top plan view of the steerable catheter with the top cover removed from the housing and with parts broken away for clarity.

FIG. 3 is a bottom plan view of the steerable catheter with the bottom cover removed from the housing and with parts broken away for clarity.

FIG. 4 is a side cross-sectional view of the steerable catheter according to the preferred embodiment of the present invention.

FIG. 5 is an exploded view of the control wheel of the housing according to the preferred embodiment of the present invention.

FIG. 6 is an enlarged view of the flexible outer end portion of the elongate tube means of the steerable catheter taken from the circled portion of FIG. 4 and rotated ninety (90) degrees.

FIG. 7 is an enlarged front view of the flexible outer end portion of the elongate tube means of the steerable catheter taken along line 7-7 of FIG. 6.

FIG. 8 is a top plan view of the steerable catheter with the top cover removed from the housing and with the control wheel rotated so as to move the flexible outer end portion of the elongate tube means of the steerable catheter to the right.

FIG. 9 is a top plan view of the steerable catheter with the top cover removed from the housing and with the control wheel rotated so as to move the flexible outer end portion of the steerable catheter to the left.

FIG. 10 is a side view of the steerable catheter having the fiberoptic scope sheath attached to an access port in the housing according to a preferred embodiment of the present invention.

FIG. 11 is an enlarged view of the circled portion of the steerable catheter having the fiberoptic scope sheath from FIG. 10 with parts broken away for clarity.

FIG. 12 is a cross-sectional view of the steerable catheter with the fiberoptic scope sheath taken along line 12-12 of FIG. 10 according to the preferred embodiment of the present invention.

FIG. 13 is a top plan view of the steerable catheter according to the present invention with the top cover removed from the housing and with parts broken away for clarity illustrating another embodiment of the control means for the catheter.

FIG. 14 is a bottom plan view of the steerable catheter according to the present invention with the bottom cover removed from the housing and with parts broken away for clarity illustrating another embodiment of the control means for the catheter.

FIG. 15 is a side view of the steerable catheter according to the present invention with parts broken away for clarity illustrating another embodiment of the control means for the catheter.

FIG. 16 is an exploded view of the control wheel according to another embodiment of the present invention.

FIG. 17 is an enlarged view of the flexible outer end portion of the elongate tube means of the steerable catheter according to another embodiment of the present invention taken from the circle portion in FIG. 15 and rotated ninety (90) degrees.

FIG. 18 is an enlarged front view of the flexible outer end portion of the elongate tube means of the steerable catheter according to another embodiment of the present invention taken along line 18-18 of FIG. 17.

FIG. 19 is a top view with the top cover of the housing removed therefrom according to another embodiment of the present invention and illustrating the movement to the flexible outer end portion of the elongate tube means of the steerable catheter.

FIG. 20 is a top view with the top cover of the handle member removed therefrom according to another embodiment of the present invention and illustrating the movement to the flexible outer end portion of the elongate tube means of the steerable catheter.

Description Of A Preferred Embodiment

The present invention now will be described more

fully hereinafter with reference to the accompanying drawings in which a preferred embodiment of the invention is shown. Like numbers refer to like elements throughout.

Referring now to FIG. 1, shown is an environmental view of a preferred embodiment of the steerable catheter **30** having distal **35** and proximal **45** ends according to the present invention. The steerable catheter **30** is being held in the hands of a catheter operator, such as a physician. The steerable catheter **30** has a housing **50**, an elongate tube means **80**, and a proximal tube **120**. The elongate tube means **80** has a first tube and a second tube **100**. Two lumens **94**, **95** (FIG. 7) extend longitudinally from the distal end **35** of the catheter, through the first **90** and second **100** tubes of the elongate tube means **80** and into the housing **50**. The first tube **90** is formed of a material of such a stiffness so as to maintain the first tube **90** in a substantially straight condition in the absence of an external force applied thereto. It is understood that a substantially straight condition would generally mean that the tube in not generally bendable but a certain amount of arc may occur under some conditions or application of an external force as previously mentioned. The second tube **100** is generally more flexible than the first tube **90**. The elongate tube means **80** in this embodiment comprises the first tube **90** and the second tube **100**, but this invention would include using one, two, or more tubes.

The housing **50** is of such a size as to be readily held in the hand of the catheter operator or other user. Access ports **161**, **162** are provided in the housing **50** for accessing the two lumens **94**, **95** within the elongate tube means **80**. One end **91** of the first tube **90** is connected to the housing **50** and then the first tube **90** extends outwardly therefrom. The second tube **100**, in turn, extends longitudinally from a second end **92** of the first tube **90**. An end **102** of the second tube **100** forms the distal end **35** of the steerable catheter **30**. The proximal tube **120** extends longitudinally through the housing **50** and extends longitudinally from the housing **50**. A first end **121** (not shown in this view) of the proximal tube **120** accesses the first end **91** of the tube within the housing **50**. The connector **140** attached to the second end **122** of the proximal tube **120** forms the proximal end **45** of the steerable catheter **30**.

A control wheel **60** is mounted to the housing **50** to aid in guiding and steering the distal end **35** of the steerable catheter **30**. The control wheel is generally circular in shape and has a front end **61**, a back end **62**, a top end **63**, a bottom end **64**, and two side ends **66**, **67**. Lobes **68**, **69** are located on the two side ends **66**, **67** of the control wheel. A tip direction indicator **70** is located on a top end **63** of the control wheel **60**. The tip direction indicator **70** lies in a longitudinal direction with respect to the upper surface **55** of the housing **50**. The distal end **35** of the steerable catheter **30** moves by rotating the control wheel **60** via the lobes **68**, **69** on the side ends **66**, **67** of the control wheel **60**. The tip direction indicator **70**, in turn, rotates clockwise and counterclockwise to a position indicating the direction and angular attitude of the distal end **35**. Position markers **58** are located on the upper surface **55** of the housing **50** around the top end **63** of the control wheel **60** to thereby mark the relative angular attitude of the distal end **35** of the steerable catheter **30** as it is being deflected and controlled.

FIGS. 2-7 illustrate the internal construction of the steerable catheter **30** according to the invention. In FIGS. 2 and 3, the top cover **56** and bottom cover **57** are each respectively removed from the housing **50** to clarify the construction therein. These views illustrate the attachment of the first end **121** of the proximal tube **120** to the first end **91** of the first tube **90**. These views also illustrate the placement of a portion of the proximal tube **120** within the housing **50**.

The side cross-sectional view of FIG. 4 further illustrates the connection of the ends of the proximal tube **120**, the first tube **90**, and the second tube **100** inside and outside the housing **50**. This view also illustrates the mounting of the control wheel **60** within the housing **50** and with respect to the proximal tube **120**.

Referring again to FIGS. 2 and 3, two guide wires **201**, **202** longitudinally extend from the distal end **35** of the steerable catheter **30** through the second tube **100** and through the first tube **90**. The guide wires **201**, **202**, in turn, extend from the first end **91** of the first tube **90**, around wire guide members **206**, **207**, and attach to the control wheel **60**. Hence, when the control wheel **60** rotates, the guide wires **201**, **202** move to thereby provide movement and control of the distal end **35** of the steerable catheter **30**.

FIG. 5 is an exploded perspective view of the control wheel **60** showing the connection of the guide wires **201**, **202** therein. The inner ends of the guide wires **201**, **202** within the housing **50** wrap around a circular hub base **213** on the bottom end **64** of the control wheel **60**. The guide wires **201**, **202** are secured to a wire receptacle **212** in the hub base **213** by a sleeve **214** and screw **216**. The outer ends of the guide wires **201**, **202** are sonic welded to the second tube **100**. Plugs in the second tube **100** may also be used to connect the guide wires **201**, **202** at outer ends.

This particular arrangement of the wires with the control wheel makes the wheel self-locking as the wheel rotates within the housing. Friction (f) is caused by the wire pull (W) acting as a normal force on the housing **50**. Since the desire of the user is that the wheel not freely rotate during use, this requirement can be satisfied if the moment due to the wire pull ($M1 = W \times r$, where r is the radius of the hub base) does not exceed the moment due to friction ($M2 = f \times R$, where R is the radius of the control wheel **60**). Since $f = \mu \times W$ (where μ is the coefficient of friction), then by substitution $M2 = \mu \times W \times R$. If the moment due to the wire pull (M1) is less than the moment due to friction (M2), then $W \times r < \mu \times W \times R$. So if $r/R < \mu$ then the wheel will not rotate by wire pull.

The control wheel **60** and the inner ends of the guide wires **201, 202** cooperate as described to control the angular attitude **220** of the second tube **100**. The control wheel **60** and guide wires **201, 202** cooperate to limit the angular attitude of the second tube **100** to angular adjustments in a common plane extending generally parallel to the upper surface of the housing **50**. The angular adjustments **220** in all other planes is obtained by rotation of the user's hand so that more control of the attitude of the second tube **100** is obtained during use of the catheter **30**. Detents are also located in the control wheel at zero (0), fifteen (15), and thirty (30) degrees with respect to the angular attitude **220** of the distal end **35** of the catheter **30**. These detents, however, may not be used at all or be located at various angular attitude **220** positions.

FIGS. 6 and 7 illustrate the distal end **35** of the steerable catheter **30** and the construction of the guide wires **201, 202** and lumens **94, 95** therein. FIG. 6 is an enlarged view of the flexible tube portion **100** and the first tube **90** taken from the circled portion of FIG. 4. FIG. 7 is a front view of the distal end **35** of the steerable catheter **30** taken along line 7-7 of FIG. 6. Along with the guide wires **201, 202**, the second tube **100** and the first tube **90** of the elongate tube means **80** have two working lumens **94, 95** extending longitudinally from the distal end **35**, through the second tube **100**, through the first tube **90**, and into the housing **50**. The lumens **94, 95** provide access for a variety of surgical tools, fluids, and other materials, such as radiographic contrast materials, angioplasty balloons, fiberoptic scopes, laser lights, and cutting instruments. This access enables the physician or catheter operator to simultaneously steer the catheter while also using the various surgical tools, fluids, and other materials as needed in the procedure.

FIGS. 8 and 9 are shown to further illustrate the controlled movement of the distal end **35** of the steerable catheter **30** via rotation of the control wheel **60**. FIGS. 8 and 9, similar to FIG. 2, are taken from a top view with the top cover **58** of the housing **50** removed therefrom and with parts broken away for clarity. As can be seen from FIGS. 8 and 9, the distal end **35** moves horizontally toward the direction of the tip direction indicator **70** located on a top end **63** of the control wheel **60**. The hand of the operator rotates the control wheel **60** by movement of the lobes **68, 69** on the side ends **66, 67** thereof. The rotation of the control wheel **60** via the lobes **68, 69** causes tension in one direction or the other to be place upon the guide wires **201, 202** wrapped around the hub base **213** to thereby move the distal end **35** a controlled or limited amount. The construction of the control wheel **60** and the guide wires **201, 202** is such that the angular attitude **220** of the distal end **35** is no greater than thirty (30) degrees.

Referring now to FIGS. 10-12, the fiberoptic scope sheath **250** of the preferred embodiment of the steerable catheter 30 will now be discussed. As shown in FIG. 10 with the fiberoptic scope sheath **250** enlarged for illustrative purposes, the fiberoptic scope sheath **250** connects to either of the access ports **161, 162**. The fiberoptic scope sheath **250** provides feedback to the operator of the steerable catheter **30** on the positional location of a fiberoptic scope **290** or the like when the scope **290** extends into a lumens **94, 95** of the catheter **30**. A fiberoptic scope **290** generally has a small diameter and may be fragile when pushed into the body cavity or vessel. Because the fiberoptic scope **290** is not radiopaque, the scope tip location in relation to the distal end **35** of the steerable catheter **30** may be undetectable to an imaging screen supplementing the fiberoptic scope image, such as that provided by a fluoroscope or the like. A fluoroscope or the like may be used to indicate the location of the distal end **35** of the catheter **30**. The fiberoptic scope sheath **250**, in turn, provides imaging indication, control, and protection for the fiberoptic scope **290** when the scope **290** is used with the steerable catheter **30**.

As shown in FIGS. 10 and 11, the fiberoptic scope sheath **250** essentially terminates at the access to the lumen **94** and provides the imaging indication, control, and protection discussed above. FIG. 12 is a cross-sectional view of the elongate tube means **40** having the fiberoptic scope sheath **250** thereon taken along line 12-12 of FIG. 10. The fiberoptic scope sheath **250**, as seen in these views has a first sheath tube **255** with first **256** and second **257** ends, and inner **258** and outer **259** tube walls. The inner tube wall **258** of the first tube **255** longitudinally receives the fiberoptic scope **290** through the first end **256** of the first sheath tube **255**. A second sheath tube **260** having first **261** and second ends **262**, and inner **263** and outer **264** tube walls longitudinally receives the first sheath tube **255**. The inner tube wall **263** of the second tube **260** has ribs **270** which engage the outer tube wall **259** of the first sheath tube **255**. The second end **262** of the second sheath tube **260** engages a connector **280** which is adapted to connect to one of the access ports **161, 162** in the housing **50**. In turn, the fiberoptic scope **290** accesses one of the lumens **94, 95** of the steerable catheter **30** through the first sheath tube **255** and into one of the access ports **161, 162**. FIG. 11 also shows a cross-sectional enlargement of seals **165** in the access ports **161, 162**. The seals are formed of an elastomeric material such as silicone rubber and have a very small axial opening therethrough that permits a small object such as the fiberoptic scope **290** or the like to enter, but which otherwise prevents fluid flow in either direction, and thus protects the lumens **94, 95** from receiving contaminants or the like therein.

FIGS. 13-20 will now be discussed to illustrate the construction of another embodiment of the steerable catheter **30'** of the present invention. Similar elements in FIGS. 13-20 are labeled with prime notation corresponding to FIGS. 1-12 and are not described further herein. In FIG. 18, the front view of the distal end **35'** of the steerable catheter **30'** taken along line 18-18 of FIG.

17 is shown. This view shows rectangular-shaped guide wires **501**, **502** instead of the circular-shaped guide wires **201**, **202** of the preferred embodiment of the steerable catheter **30**. Although the overall construction of the other embodiment is generally the same as a preferred embodiment, the rectangular-shaped guide wires **501**, **502** provide additional control for the movement of the distal end **35'** of the catheter **30'**.

FIGS. 13, 14 and 16 illustrate the engagement and connection of the guide wires **501**, **502** of the other embodiment of the steerable catheter **335** to the control wheel **60'** and housing **50'**. The guide wires **501**, **502** extend from the distal end **35'**, through the elongate tube means **40'**, and into the housing **50'**. Inside the housing **50'**, the guide wires **501**, **502** exit the elongate tube means **40'**, extend through the control wheel **60'**, and terminate into wire terminals **356**, **357**. The hub base **413** of the control wheel **60'** of this embodiment is in the form of a cam which places tension on the guide wires **501**, **502** when the control wheel **60'** is rotated clockwise or counter-clockwise. The control wheel 60' is located within the housing **50'** in a center portion thereof for laterally moving the guide wires **501**, **502** to thereby control the flexible outer end portion of the tube means **80'** by moving the guide wires **501**, **502**. The cam hub base **413** depending from a center portion of the control wheel **60'** bears against and laterally displaces the portions of the guide wires **501**, **502** adjacent the cam hub base **413** so that the guide wires **501**, **502** are urged longitudinally and thereby move the flexible outer end portion.

FIGS. 19 and 20 illustrate the rotation of the control wheel **60'** to thereby cause movement and adjustments in the angular attitude **220'** of the distal end **35'** of the steerable catheter **30'**. The engagement and connection of the guide wires **501**, **502** in the distal tube **40'** and the control wheel **360** provide the additional control for the distal end **35'** of the steerable catheter **30'**.

In the drawings and specification, there have been disclosed typical preferred embodiments of the invention and, although specific terms are employed, they are used in a generic and descriptive sense only and not for the purposes of limitation, the scope of the invention being set forth in the following claims.

Claims

1. A steerable catheter (30) for use in body vessels or cavities, comprising:

   elongate tube means (80) having at least a pair of lumens (94, 95) extending longitudinally through said elongate tube means (80) and being formed of material having sufficient stiffness to maintain said elongate tube means (80) in a substantially straight condition in the absence of an external force applied thereto, said elongate tube means (80) having a flexible distal end portion (35);

   a housing (50) having an upper surface (55) and a lower surface and being of such a size as to be readily held in the hand of a user, and connected to said elongate tube means (80);

   guide wires (201, 202) having proximal ends connected to said housing (50) and extending outwardly therefrom through said elongate tube means (80), distal ends of said guide wires (201, 202) being connected to said flexible distal end portion (35) of said elongate tube means (80); and

   guide wire control means carried by said housing (50) and cooperating with proximal end portions of said guide wires (201, 202) for controlling the angular attitude (220) of said flexible distal end portion (35) of said elongate tube means (80), said guide wires (201, 202) and control means cooperating to limit the angular attitude of said flexible distal end portion (35) of said elongate cube means (80) to angular adjustments (220) in a common plane extending generally parallel to said upper surface (55) of said housing (50) and wherein the angular adjustment (220) of said flexible distal end portion (35) of said elongate cube means (80) in all other planes is obtained by rotation of the user's hand;

   said steerable catheter

   characterized by

   said housing further including recessed side peripheries for increased handling and control of said housing and said guide wire control means being carried by said housing within said recessed side peripheries for increasing the ease of control of said distal end portion (35) when said housing is held in the hand of a user thereof;

   a pair of access ports (161, 162) positioned within said upper surface (55) of said housing for accessing working lumen (94, 95) of said elongate tube means (80); and

   means positioned within said housing (50) for connecting said access ports (161, 162) to said lumens (94, 95) of said elongate tube means (80); said connecting means includes a piping connector (140) having a plurality of openings therein, said openings connecting said pair of access ports (161, 162) positioned in said upper surface (55) of said housing (50) with said working lumens (94, 95) of said elongate tube means (80).

2. A catheter (30) according to claim 1,
   wherein said elongate tube means (80) has a proximal end (45) connected to said housing (50) and extends outwardly therefrom, and said at least one pair of working lumen (94, 95) longitudinally

extends from said distal end portion (35) to said proximal end (45), and
wherein said proximal ends of said guide wires (201, 202) are positioned within said housing (50).

3. A catheter (30) according to Claim 1 or 2, wherein said elongate tube means (80) comprises a first tube (90) extending outwardly from said housing (50) and a second tube (100) connected to said first tube (90) and extending outwardly therefrom, said first tube (90) being more rigid than said second tube (100), said second tube (100) including said flexible distal end portion (35) of said elongate tube means (80).

4. A catheter (30) according to Claim 1 or 2, further comprising an elongate proximal tube (120) having one end (91) connected to said housing (50) and extending outwardly therefrom, said proximal tube (120) further having a lumen extending longitudinally through said proximal tube (120) and accessing at least one of said lumens (94, 95) in said elongate tube means (80).

5. A catheter (30) according to Claim 4, wherein said proximal tube (120) connects to said connecting means within said housing (50) and accesses at least one of said lumens (94, 95) in said elongate tube means (80) through said connecting means.

6. A catheter (30) according to Claim 1 or 2, wherein one of said lumens (95) extending longitudinally through said elongate tube means (80) has a larger diameter than the other lumen (94) extending longitudinally through said elongate tube means (80).

7. A catheter (30) according to Claim 1 or 2, wherein said flexible distal end portion (35) of said elongate tube means (80) converges to form a tip (102) of the catheter (30) for ease of access into and through a body vessel or cavity, skin, or tissue, said tip of the catheter (30) being formed so that each of said pair of lumens (94, 95) distally terminate on opposite converging sides of said converging tip (102).

8. A catheter (30) according to Claim 1 or 2, further comprising a central axis extending longitudinally from said flexible distal end portion (35) of said elongate tube means (80), through said elongate tube means (80), and into said housing (50), and wherein said control means comprises a rotating control wheel (60) connected to said proximal ends of said two guide wires (201, 202) so that rotation of said control wheel (60) guides the flexible distal end portion (35) of said elongate tube means (80) in an angular attitude (220) from said longitudinally extending central axis in a generally transverse direction therefrom.

9. A, catheter (30) according to Claim 8, wherein said housing (50) further comprises indicating means connected to said upper surface (55) of said housing (50) adjacent said access ports (161, 162) for correspondingly indicating the angular attitude (220) of said flexible distal end portion (35) during rotation of said control wheel (60).

10. A catheter (30) according to Claim 1 or 2, wherein said control means comprises a control wheel (60) located within said housing (50) in a medial portion thereof for laterally moving said guide wires (201, 202) to thereby control the flexible distal end portion (35) by moving said guide wires (201, 202) and having a cam hub (213) depending from a center portion of said control wheel (60) for bearing against and laterally displacing the proximal end portions of said guide wires (201, 202) adjacent said cam hub (213) so that said guide wires (201, 202) are urged longitudinally and thereby move said flexible distal end portion (35).

11. A catheter (30) according to Claim 10, wherein said guide wires (201, 202) attach to a proximal end portion (45) of said housing (50) and have a non-circular cross-section.

12. A catheter (30) according to claim 10, characterized by

a manifold positioned within said housing (50) for connecting said access ports (161, 162) to at least one of said lumens (94, 95) of said elongate tube means (80).

13. A catheter (30) according to Claim 12, wherein said guide wire control means includes a control wheel (60) having a cam hub (213) adjacent said guide wires (201, 202) that cooperates with said proximal end portions of said guide wires (201, 202) for bearing against the proximal end portions of said guide wires (201, 202) so that said guide wires (201, 202) are urged longitudinally and thereby move said flexible distal end portion (35).

14. A catheter (30) according to Claim 13, wherein said manifold comprises a piping connector (140) having a plurality of openings therein, said openings connecting said two access ports (161, 162) positioned in the upper surface (55) of said housing (50) with one of said pair of lumens (94, 95) of said elongate tube means (80) and connecting said proximal tube with the other of said pair of lumens (94, 95) of said elongate tube means (80).

15. A catheter according to claim 12, further comprising fiber optic sheath means (250) longitudinally extending from at least one of said

access ports (161, 162) of said housing (50) and adapted to receive a fiberoptic scope (290) or the like for inserting the fiberoptic scope (290) or the like into at least one lumen (94, 95) of said elongate tube means (80).

16. A catheter (30) according to Claim 13, wherein said control wheel (60) further includes a pair of lobes (68, 69) each extending outwardly from opposite side portions of said housing (50) to thereby rotate said control wheel (60) and move said flexible distal end portion (35) of said elongate tube means (80).

Patentansprüche

1. Steuerbarer Katheter (30) zum Einsatz in Körpergefäßen oder - hohlräumen, mit

länglichen Rohrmitteln (80), die wenigstens ein Paar in Längsrichtung durch die länglichen Rohrmittel (80) hindurch verlaufende Röhren (94, 95) aufweisen und aus einem Material hergestellt sind, das mit einer ausreichenden Steifigkeit versehen ist, um die länglichen Rohrmittel (80) in einem im wesentlichen geraden Zustand beim Fehlen einer auf sie aufgebrachten äußeren Kraft zu halten, wobei die länglichen Rohrmittel (80) einen flexiblen distalen Endabschnitt (35) aufweisen;
einem Gehäuse (50), das eine Oberseite (55) sowie eine Unterseite aufweist und so groß ist, daß es ohne weiteres in der Hand eines Benutzers gehalten werden kann, und das mit den länglichen Rohrmitteln (80) verbunden ist;
Führungsdrähten (201, 202), die proximale, mit dem Gehäuse (50) verbundene Enden aufweisen und sich von diesem aus durch die länglichen Rohrmittel (80) hindurch nach außen erstrecken, wobei distale Enden der Führungsdrähte (201, 202) mit dem flexiblen distalen Endabschnitt (35) der länglichen Rohrmittel (80) verbunden sind; und mit
einer Führungsdraht-Steuereinrichtung, die von dem Gehäuse (50) gehalten wird und mit proximalen Endabschnitten der Führungsdrähte (201, 202) zum Steuern der Winkelstellung (220) des flexiblen distalen Endabschnitts (35) der länglichen Rohrmittel (80) zusammenwirkt, wobei die Führungsdrähte (201, 202) und die Steuereinrichtung zusammenwirken, um die Winkelstellung des flexiblen distalen Endabschnitts (35) der länglichen Rohrmittel (80) auf Winkeleinstellungen (220) in einer gemeinsamen Ebene zu begrenzen, die allgemein parallel zu der Oberseite (55) des Gehäuses (50) verläuft, und wobei die Winkeleinstellung (220) des flexiblen distalen Endabschnitts (35) der länglichen Rohrmittel (80) in allen anderen Ebenen durch Drehung der Hand des Benutzers erreicht wird;
wobei der steuerbare Katheter
dadurch gekennzeichnet ist, daß
das Gehäuse ferner zurückgesetzte seitliche Begrenzungsflächen zur verbesserten Handhabung und Bedienung des Gehäuses aufweist und daß die Führungsdraht-Steuereinrichtung von dem Gehäuse innerhalb der zurückgesetzten seitlichen Begrenzungsflächen gehalten wird, um die Steuerung des distalen Endabschnitts (35) zu vereinfachen, wenn das Gehäuse in der Hand seines Benutzers gehalten ist;
ein Paar Zugangsöffnungen (161, 162) in der Oberseite (55) des Gehäuses angeordnet sind, um zu den Behandlungsröhren (94, 95) der länglichen Rohrmittel (80) Zugang zu haben; und daß
in dem Gehäuse (50) Mittel angeordnet sind, die die Zugangsöffnungen (161, 162) mit den Röhren (94, 95) der länglichen Rohrmittel (80) verbinden, wobei die Verbindungsmittel einen Rohrverbinder (140) mit einer Mehrzahl in diesem angeordneter Öffnungen aufweisen, die das Paar in der Oberseite (55) des Gehäuses (50) angeordneter Zugangsöffnungen (161, 162) mit den Behandlungsröhren (94, 95) der länglichen Rohrmittel (80) verbinden.

2. Katheter (30) nach Anspruch 1,

bei dem die länglichen Rohrmittel (80) ein proximales Ende (45) aufweisen, das mit dem Gehäuse (50) verbunden ist, und von diesem aus nach außen verlaufen und bei dem wenigstens ein Paar Behandlungsröhren (94, 95) sich in Längsrichtung von dem distalen Endabschnitt (35) zu dem proximalen Ende (45) erstreckt, und
bei dem die proximalen Enden der Führungsdrähte (201, 202) innerhalb des Gehäuses (50) angeordnet sind.

3. Katheter (30) nach Anspruch 1 oder 2,

bei dem die länglichen Rohrmittel (80) ein erstes Rohr (90), das vom Gehäuse (50) aus nach außen verläuft, und ein zweites Rohr (100) aufweisen, das mit dem ersten Rohr (90) verbunden ist und von diesem aus sich nach außen erstreckt, wobei das erste Rohr (90) steifer als das zweite Rohr (100) ist und das zweite Rohr (100) den flexiblen distalen Endabschnitt (35) der länglichen Rohrmittel (80) aufweist.

4. Katheter (30) nach Anspruch 1 oder 2,

ferner mit einem länglichen proximalen Rohr (120), das ein mit dem Gehäuse (50) verbundenes Ende (91) aufweist und sich von diesem aus nach außen erstreckt und das (120) ferner eine Röhre aufweist, die in Längsrichtung durch das proximale Rohr (120) verläuft und auf wenigstens eine der Röhren (94, 95) in den länglichen Rohrmitteln (80) zugreift.

5. Katheter (30) nach Anspruch 4,

bei dem das proximale Rohr (120) mit den Verbindungsmitteln innerhalb des Gehäuses (50) verbunden ist und auf wenigstens eine der Röhren (94, 95) in den länglichen Rohrmitteln (80) durch die Verbindungsmittel zugreift.

6. Katheter (30) nach Anspruch 1 oder 2,

bei dem eine der Röhren (95), die sich in Längsrichtung durch die länglichen Rohrmittel (80) erstreckt, einen größeren Durchmesser als die andere Röhre (94) aufweist, die sich in Längsrichtung durch die länglichen Rohrmittel (80) erstreckt.

7. Katheter (30) nach Anspruch 1 oder 2,

bei dem der flexible distale Endabschnitt (35) der länglichen Rohrmittel (80) konvergiert, um eine Spitze (102) des Katheters (30) für einen leichten Zugang in ein Körpergefäß oder einen Körperhohlraum, in Haut oder Gewebe sowie durch diese hindurch auszubilden, wobei die Spitze des Katheters (30) so geformt ist, daß jede des Paars Röhren (94, 95) distal auf einander gegenüberliegenden konvergierenden Seiten der konvergierenden Spitze (102) endet.

8. Katheter (30) nach Anspruch 1 oder 2,

ferner mit einer Mittelachse, die sich in Längsrichtung von dem flexiblen distalen Endabschnitt (35) der länglichen Rohrmittel (80) aus durch diese (80) in das Gehäuse (50) hinein erstreckt, wobei die Steuereinrichtung ein Steuer-Drehrad (60) aufweist, das mit den proximalen Enden der zwei Führungsdrähte (201, 202) verbunden ist, so daß ein Drehen des Steuerrads (60) den flexiblen distalen Endabschnitt (35) der länglichen Rohrmittel (80) in eine Winkelstellung (220) von der in Längsrichtung verlaufenden Mittelachse aus in eine allgemein dazu querverlaufende Richtung führt.

9. Katheter (30) nach Anspruch 8,

bei dem das Gehäuse (50) ferner Anzeigemittel aufweist, die mit der Oberseite (55) des Gehäuses (50) nahe der Zugangsöffnungen (161, 162) verbunden sind, um die Winkelstellung (220) des flexiblen distalen Endabschnitts (35) während einer Drehung des Steuerrades (60) entsprechend anzuzeigen.

10. Katheter (30) nach Anspruch 1 oder 2,

bei dem die Steuereinrichtung ein Steuerrad (60) aufweist, das in einem mittleren Abschnitt des Gehäuses (50) innerhalb diesem angeordnet ist, um die Führungsdrähte (201, 202) seitlich zu bewegen und dadurch den flexiblen distalen Endabschnitt (35) durch Bewegen der Führungsdrähte (201, 202) zu steuern, und das eine Nockennabe (213) aufweist, die von einem Mittelabschnitt des Steuerrades (60) herabhängt, um gegen die proximalen Endabschnitte der Führungsdrähte (201, 202) anzuliegen und diese nahe der Nockennabe (213) seitlich zu verschieben, so daß die Führungsdrähte (201, 202) in Längsrichtung angetrieben werden und dadurch den flexiblen distalen Endabschnitt (35) bewegen.

11. Katheter (30) nach Anspruch 10,

bei dem die Führungsdrähte (201, 202) an einem proximalen Endabschnitt (45) des Gehäuses (50) befestigt sind und einen nichtkreisförmigen Querschnitt aufweisen.

12. Katheter (30) nach Anspruch 10,
gekennzeichnet durch eine innerhalb des Gehäuses (50) angeordnete Rohrverzweigung zum Verbinden der Zugangsöffnungen (161, 162) mit wenigstens einer der Röhren (94, 95) der länglichen Rohrmittel (80).

13. Katheter (30) nach Anspruch 12,

bei dem die Führungsdraht-Steuereinrichtung ein Steuerrad (60) mit einer Nockennabe (213) nahe den Führungsdrähten (201, 202) aufweist, die mit den proximalen Endabschnitten der Führungsdrähte (201, 202) zum Anliegen an den proximalen Endabschnitten der Führungsdrähte (201, 202) zusammenwirkt, so daß die Führungsdrähte (201, 202) in Längsrichtung angetrieben werden und dadurch den flexiblen distalen Endabschnitt (35) bewegen.

14. Katheter (30) nach Anspruch 13,

bei dem die Rohrverzweigung einen Rohrverbinder (140) mit einer Mehrzahl in ihm ausgebil-

deter Öffnungen aufweist, die die zwei in der Oberseite (55) des Gehäuses (50) angeordneten Zugangsöffnungen (161, 162) mit einer des Paars Röhren (94, 95) der länglichen Rohrmittel (80) und das proximale Rohr mit der anderen des Paars Röhren (94, 95) der länglichen Rohrmittel (80) verbinden.

15. Katheter nach Anspruch 12,

ferner mit faseroptischen Umhüllungsmitteln (250), die sich in Längsrichtung von wenigstens einer der Zugangsöffnungen (161, 162) des Gehäuses (50) aus erstrecken und dazu eingerichtet sind, ein faseroptisches Instrument (290) oder ähnliches aufzunehmen, um das faseroptischen Instrument (290) oder ähnliches in wenigstens eine Röhre (94, 95) der länglichen Rohrmittel (80) einzuführen.

16. Katheter (30) nach Anspruch 13,

bei dem das Steuerrad (60) ferner ein Paar Nasen (68, 69) aufweist, die jeweils von einander gegenüberliegenden Seitenabschnitten des Gehäuses (50) aus sich nach außen erstrecken, um durch diese das Steuerrad (60) zu drehen und den flexiblen distalen Endabschnitt (35) der länglichen Rohrmittel (80) zu bewegen.

Revendications

1. Un cathéter orientable (30) utilisable dans des vaisseaux ou des cavités corporelles, comprenant :

un moyen tubulaire allongé (80) présentant au moins une paire de passages (94, 95) s'étendant longitudinalement à travers ledit moyen tubulaire allongé (80) et étant réalisé en une matière présentant une raideur suffisante pour maintenir ledit moyen tubulaire allongé (80) dans un état sensiblement rectiligne en l'absence d'une force externe qui lui est appliquée, ledit moyen tubulaire allongé (80) présentant une partie d'extrémité distale souple (35),

un boîtier (80) présentant une surface supérieure (55) et une surface inférieure et étant d'une dimension telle qu'il soit facilement tenu dans la main d'un utilisateur, et relié audit moyen tubulaire allongé (80) ;

des fils métalliques de guidage (201, 202) présentant des extrémités proximales reliées audit boîtier (50) et s'étendant vers l'extérieur de celui-ci à travers ledit moyen tubulaire allongé (80), les extrémités distales desdits fils métalliques de guidage (201, 202) étant reliées à ladite partie d'extrémité distale souple (35) dudit moyen tubulaire allongé (80) ; et

des moyens de commande des fils métalliques de guidage portés par ledit boîtier (50) et coopérant avec des parties d'extrémité proximale desdits fils métalliques de guidage (201, 202) pour commander la position angulaire (220) de ladite partie d'extrémité distale souple (35) dudit moyen tubulaire allongé (80), lesdits fils métalliques de guidage (201, 202) et lesdits moyens de commande coopérant pour imiter la position angulaire de ladite partie d'extrémité distale souple (35) dudit moyen tubulaire allongé (80) à des réglages angulaires (220) dans un plan commun s'étendant de manière générale parallélement à ladite surface supérieure (55) dudit boîtier (50), le réglage angulaire (220) de ladite partie d'extrémité distale souple (35) dudit moyen tubulaire allongé (80) dans tous les autres plans étant obtenu par une rotation de la main de l'utilisateur ;

ledit cathéter orientable
caractérisé par le fait que

ledit boîtier comprend en outre des parties périphériques latérales évidées pour faciliter la manoeuvre et la commande dudit boîtier, et lesdits moyens de commande des fils métalliques de guidage sont portés par ledit boîtier à l'intérieur desdites parties périphériques latérales évidées pour augmenter la facilité de commande de ladite partie d'extrémité distale ((35) lorsque ledit boîtier est tenu dans la main d'un utilisateur de celui-ci ;

une paire d'orifices d'accès (161, 162) placés à l'intérieur de ladite surface supérieure (55) dudit boîtier pour accéder à des passages de travail (94, 95) dudit moyen tubulaire allongé (80) ; et

des moyens placés à l'intérieur dudit boîtier (50) pour relier lesdits orifices d'accès (161, 162) auxdits passages (94, 95) dudit moyen tubulaire allongé (80) ; lesdits moyens de liaison comprennent un connecteur de câblage (140) présentant un ensemble d'ouvertures internes, lesdites ouvertures reliant ladite paire d'orifices d'accès (161, 162) placés dans ladite surface supérieure (55) dudit boîtier (50) avec lesdits passages de travail (94, 95) dudit moyen tubulaire allongé (80).

2. Un cathéter (30) selon la revendication 1,

dans lequel ledit moyen tubulaire allongé (80) présente une extrémité proximale (35) reliée audit boîtier (50) et s'étend vers l'extérieur de celui-ci, et ladite au moins une paire de passages de travail (94, 95) s'étend longitudinalement à partir de ladite partie d'extrémité distale (35) vers ladite partie proximale (45), et dans lequel lesdites extrémités proximales desdits fils métalliques de guidage (201, 202) sont mises en place à l'intérieur du boîtier (50).

3. Un cathéter selon la revendication 1 ou 2, dans lequel ledit moyen tubulaire allongé (80) comprend un premier tube (90) s'étendant vers l'extérieur dudit boîtier (50) et un second tube (100) relié audit premier tube (90) et s'étendant vers l'extérieur de celui-ci, ledit premier tube (90) étant plus rigide que ledit second tube (100), ledit second tube (100) comprenant ladite partie d'extrémité distale souple (35) dudit moyen tubulaire allongé (80).

4. Un cathéter (30) selon la revendication 1 ou 2, comprenant en outre un tube proximal allongé (120) présentant une extrémité (91) reliée audit boîtier (50) et s'étendant vers l'extérieur de celui-ci, ledit tube proximal (120) présentant en outre un passage s'étendant longitudinalement à travers ledit tube proximal (120) et donnant accès à au moins un desdits passages (94, 95) prévus dans ledit moyen tubulaire allongé (80).

5. Un cathéter selon la revendication 4, dans lequel ledit tube proximal (120) se relie auxdits moyens de liaison à l'intérieur dudit boîtier (50) et donne accès au moins à l'un desdits passages (94, 95) prévus dans ledit moyen tubulaire allongé (80) à travers lesdits moyen de liaison.

6. Un cathéter (30) selon la revendication 1 ou 2, dans lequel un desdits passages (95) s'étendant longitudinalement à travers ledit moyen tubulaire allongé (80) présente un diamètre plus grand que l'autre passage (94) s'étendant longitudinalement à travers ledit moyen tubulaire allongé (80).

7. Un cathéter (30) selon la revendication 1 ou 2, dans lequel ladite partie d'extrémité distale souple (35) dudit moyen tubulaire allongé (80) converge pour former une pointe (102) du cathéter (30) pour faciliter l'accès dans et à travers un vaisseau ou une cavité corporelle, la peau ou un tissu, ladite pointe du cathéter (30) étant formée de manière que chacun des passages de ladite paire de passages (94, 95) se termine distalement sur les côtés convergents opposés de ladite pointe convergente (102).

8. Un cathéter selon la revendication 1 ou 2, comprenant en outre un axe central s'étendant longitudinalement depuis ladite partie d'extrémité distale souple (35) dudit moyen tubulaire allongé (80), à travers ledit moyen tubulaire allongé (80), et jusqu'audit boîtier (50), et dans lequel lesdits moyens de commande comprennent une roue de commande rotative (60) reliée auxdites extrémités proximales desdits deux fils métalliques de guidage (201, 202) de sorte que la rotation de ladite roue de commande (60) guide la partie d'extrémité distale souple (35) dudit moyen tubulaire allongé (80) dans une position angulaire (220) par rapport audit axe central s'étendant longitudinalement dans une direction généralement transversale par rapport à celui-ci.

9. Un cathéter (30) selon la revendication 8, dans lequel ledit boîtier (50) comprend en outre des moyens indicateurs reliés à ladite surface supérieure (55) dudit boîtier (50) de manière adjacente auxdits orifices d'accès (161, 162) pour indiquer de manière correspondante la position angulaire (220) de ladite partie d'extrémité distale souple (35) au cours de la rotation de ladite roue de commande (60).

10. Un cathéter (30) selon la revendication 1 ou 2, dans lequel lesdits moyens de commande comprennent une roue de commande (60) placée à l'intérieur dudit boîtier (50) dans une partie médiane de celui-ci pour déplacer latéralement lesdits fils métalliques de guidage (201, 202) de manière ainsi à commander la partie d'extrémité distale souple (35) en déplaçant lesdits fils métalliques de guidage (201, 202) et présentant un moyeu à came (213) suspendu à une partie centrale de ladite roue de commande (60) pour porter contre les parties d'extrémité proximale desdits fils métalliques de guidage (201, 202) adjacents audit moyeu à came (213) et les déplaçant latéralement de sorte que lesdits fils métalliques de guidage (201, 202) sont poussés longitudinalement et déplacent ainsi ladite partie d'extrémité distale souple (35).

11. Un cathéter (30) selon la revendication 10, dans lequel lesdits fils métalliques de guidage (201, 202) sont fixés à une partie d'extrémité proximale (45) dudit boîtier (50) et présentent une section transversale non circulaire.

12. Un cathéter (30) selon la revendication 10, caractérisé par

un collecteur placé à l'intérieur dudit boîtier (50) pour relier lesdits orifices d'accès (161, 162) à au moins un desdits passages (94, 95) dudit moyen tubulaire allongé (80).

13. Un cathéter (30) selon la revendication 12, dans

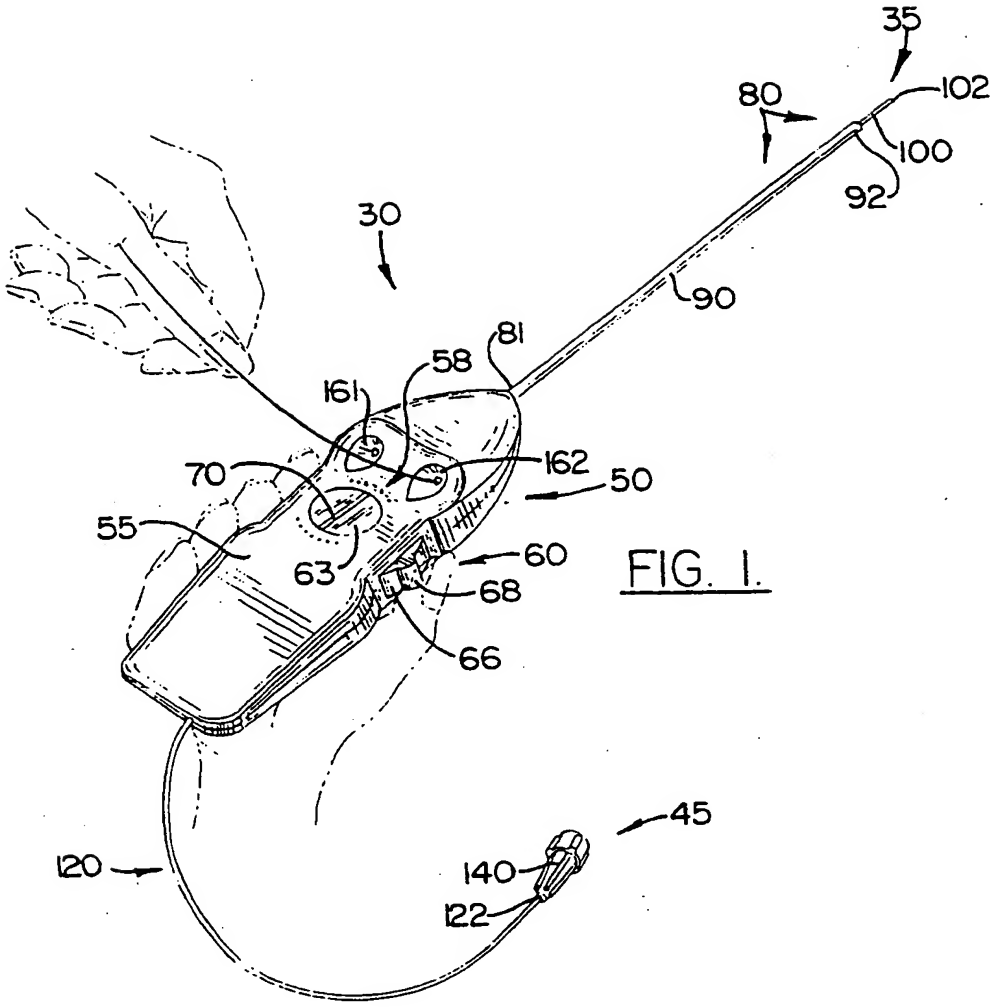
lequel lesdits moyens de commande des fils métalliques de guidage comprennent une roue de commande (60) présentant un moyeu à came (213) adjacent auxdits fils métalliques de guidage (201, 202) qui coopèrent avec lesdites parties d'extrémité proximale desdits fils métalliques de guidage (201, 202) pour porter contre les parties d'extrémités proximales desdits fils métalliques de guidage (201, 202) de sorte que lesdits fils métalliques de guidage (201, 202) sont poussés longitudinalement et déplacent ainsi ladite partie d'extrémité distale souple (35).

14. Un cathéter (30) selon la revendication 13, dans lequel ledit collecteur comprend un connecteur de câblage (140) présentant un ensemble d'ouvertures internes, lesdites ouvertures reliant lesdits orifices d'accès (161, 162) placés dans la surface supérieure (55) dudit boîtier (50) avec l'un des passages de ladite paire de passages (94, 95) dudit moyen tubulaire allongé (80) et reliant ledit tube proximal avec l'autre passage de ladite paire de passages (94, 95) dudit moyen tubulaire allongé (80).

15. Un cathéter selon la revendication 12,

comprenant en outre des moyens formant fourreau de fibroscope (250) s'étendant longitudinalement à partir d'au moins un desdits orifices d'accès (161, 162) dudit boîtier (50) et adaptés pour recevoir un fibroscope (290) ou analogue afin d'insérer le fibroscope (290) ou analogue dans au moins un passage (94, 95) dudit moyen tubulaire allongé (80).

16. Un cathéter (30) selon la revendication 13, dans lequel ladite roue de commande (60) comprend en outre une paire de lobes (68, 69) s'étendant chacun vers l'extérieur depuis des parties latérales opposées dudit boîtier (50) pour ainsi faire tourner ladite roue de commande (60) et déplacer ladite partie d'extrémité distale souple (35) dudit moyen tubulaire allongé (80).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80
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100
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140
122

FIG. 1.

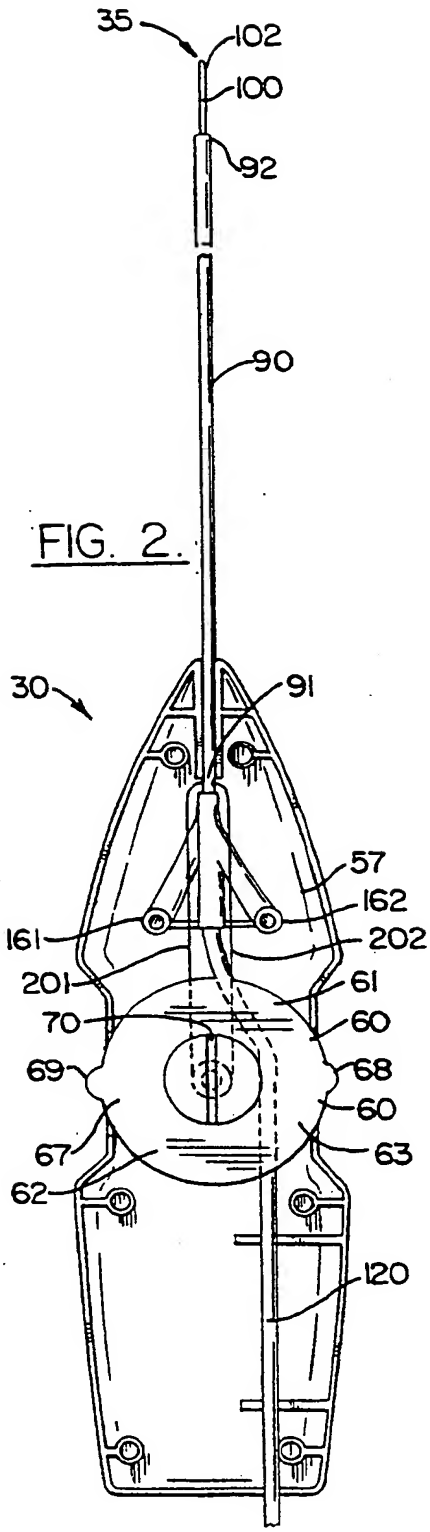
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FIG. 2.

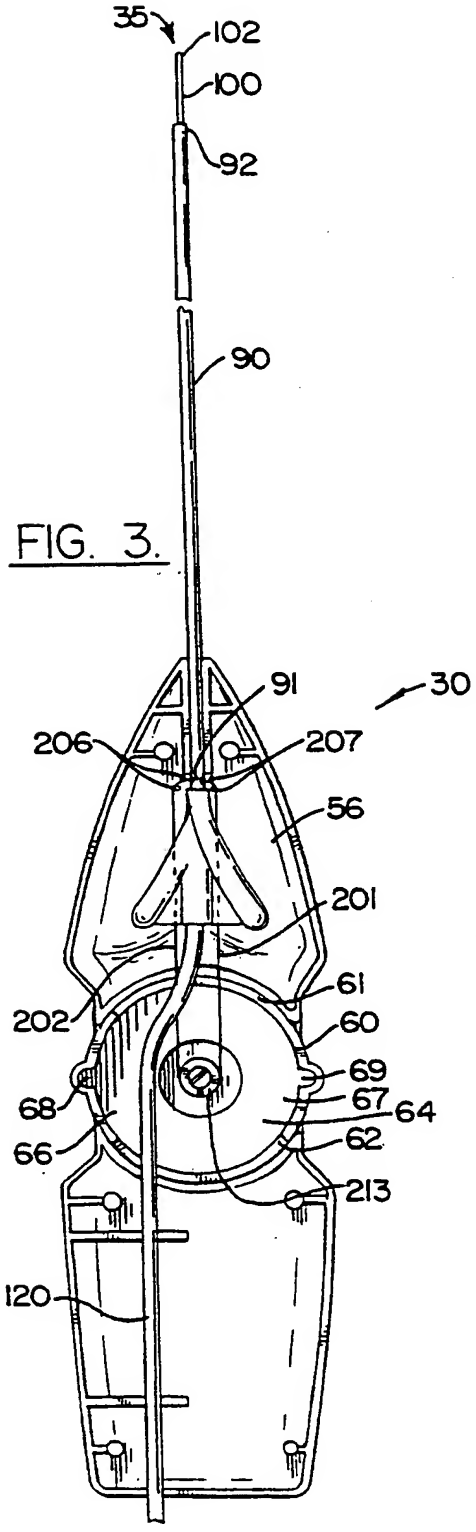
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FIG. 3.

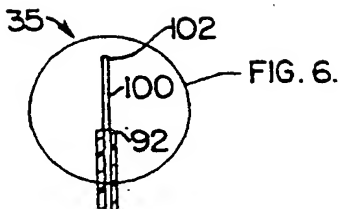


FIG. 6.

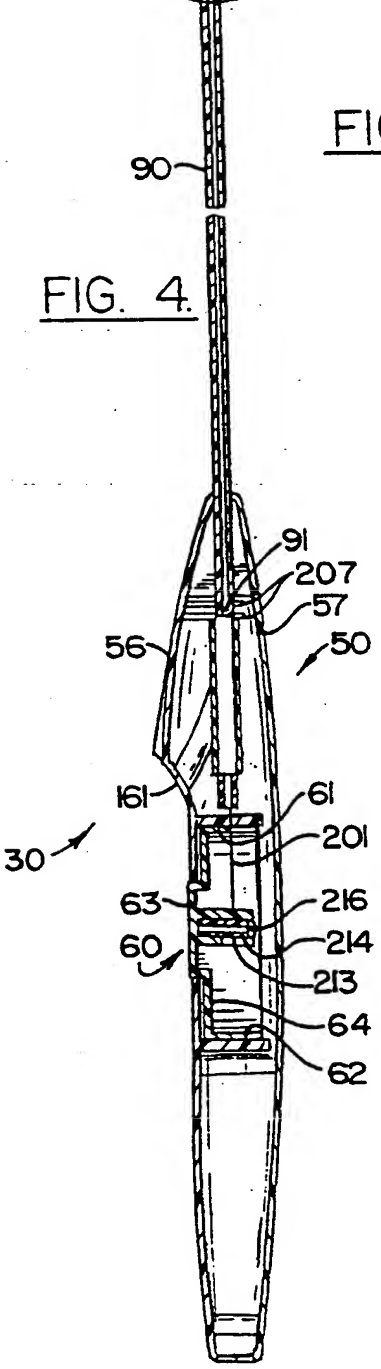
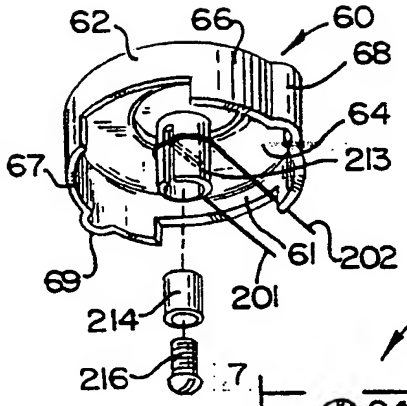


FIG. 4.

FIG. 5.



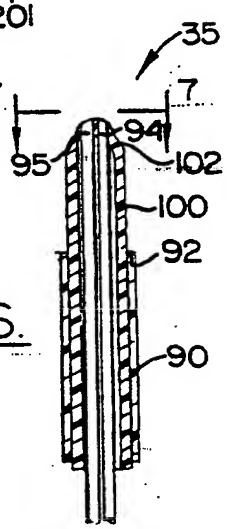
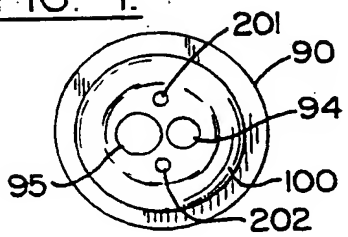


FIG. 6.

FIG. 7.



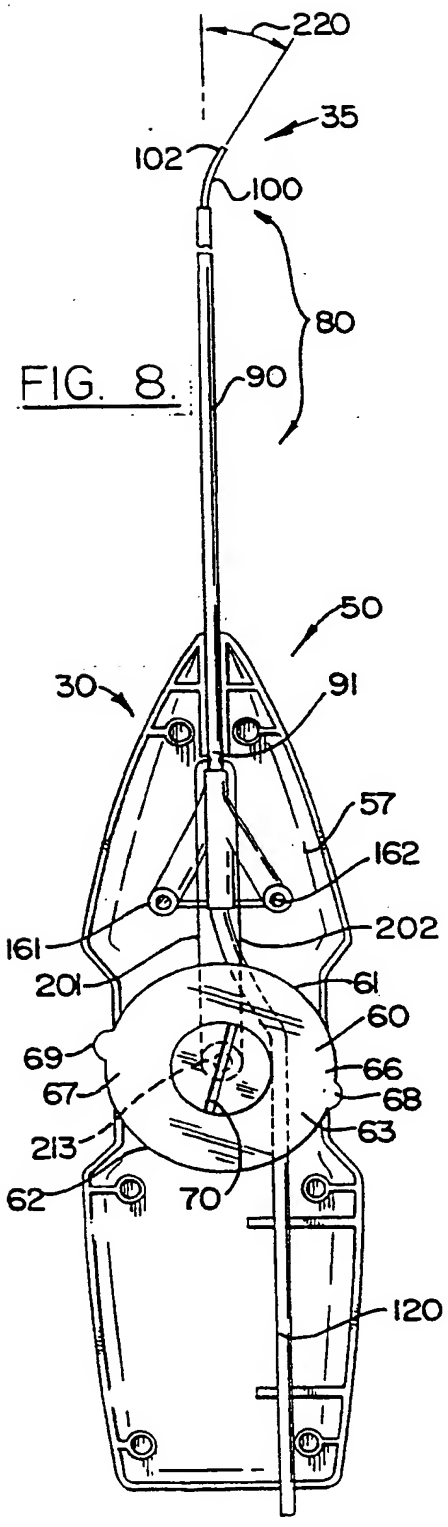

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FIG. 8.

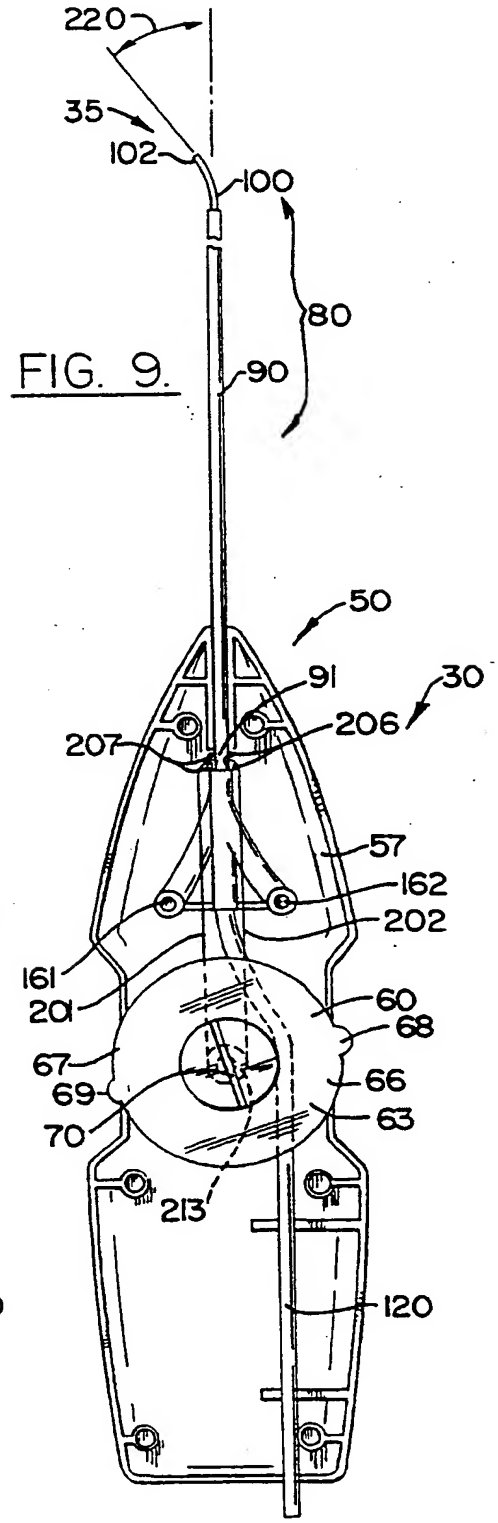
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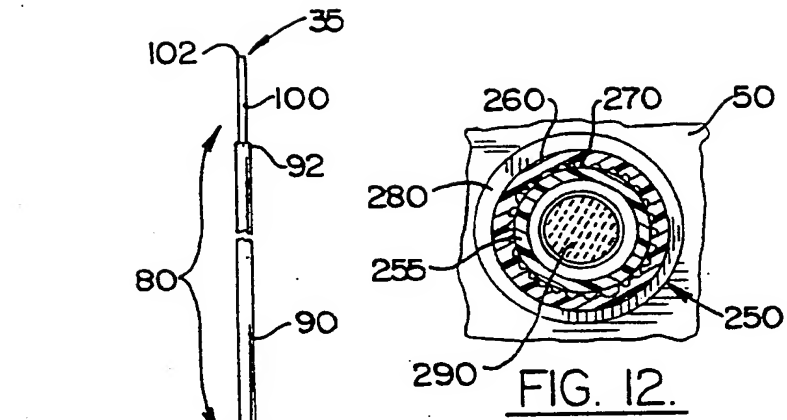
FIG. 9.



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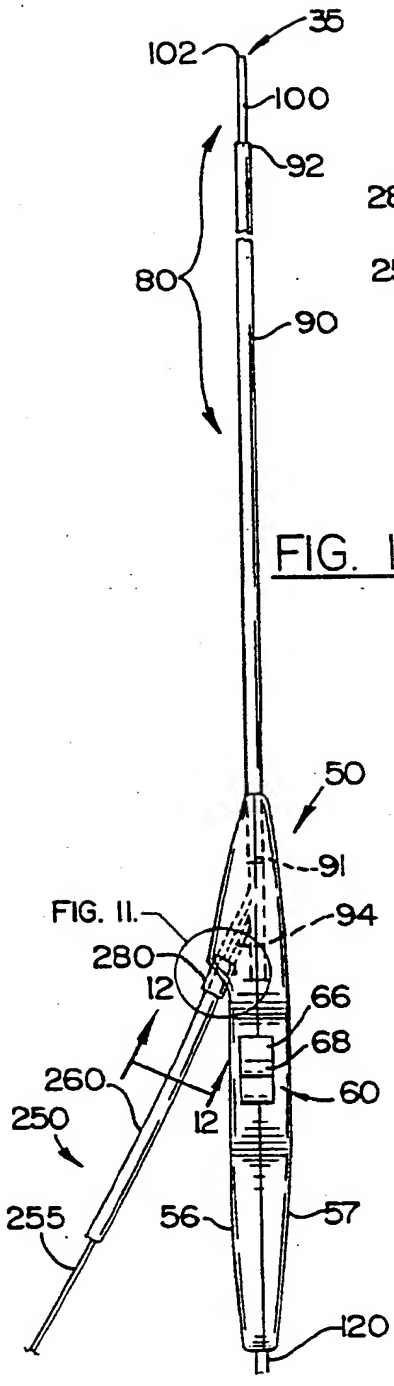

FIG. 10.

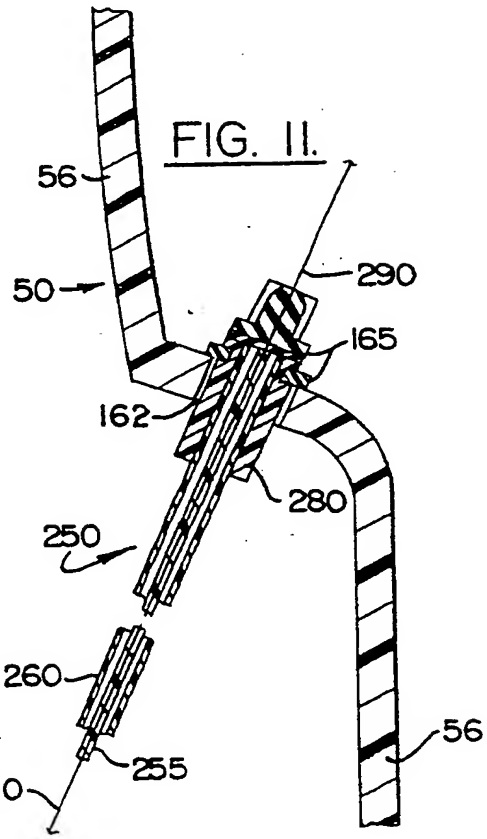

FIG. 11.

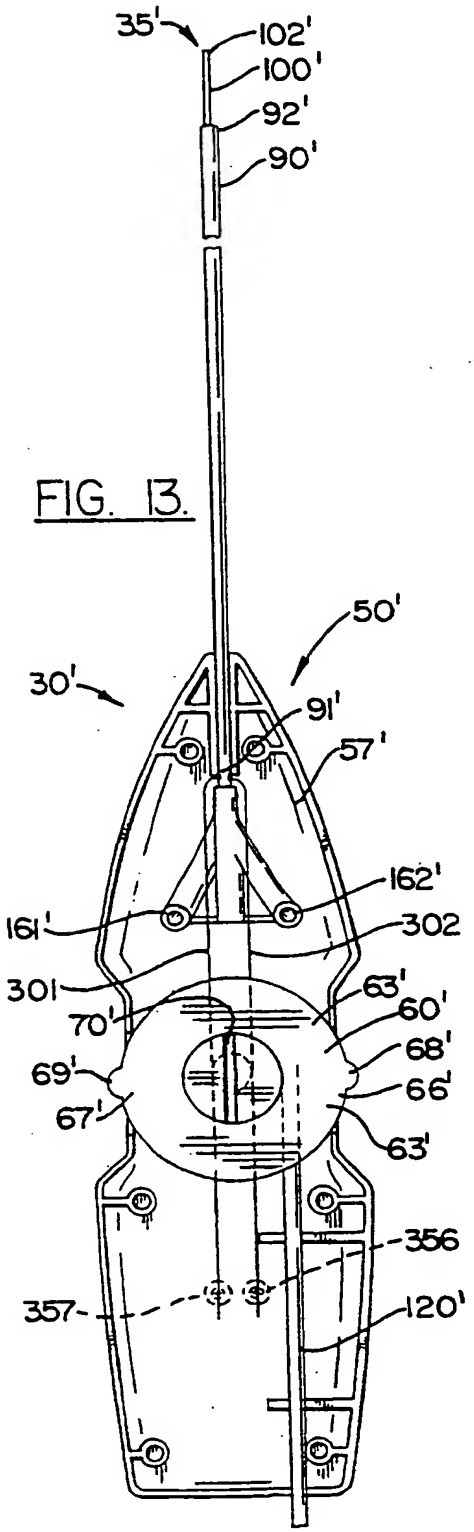
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FIG. 13.

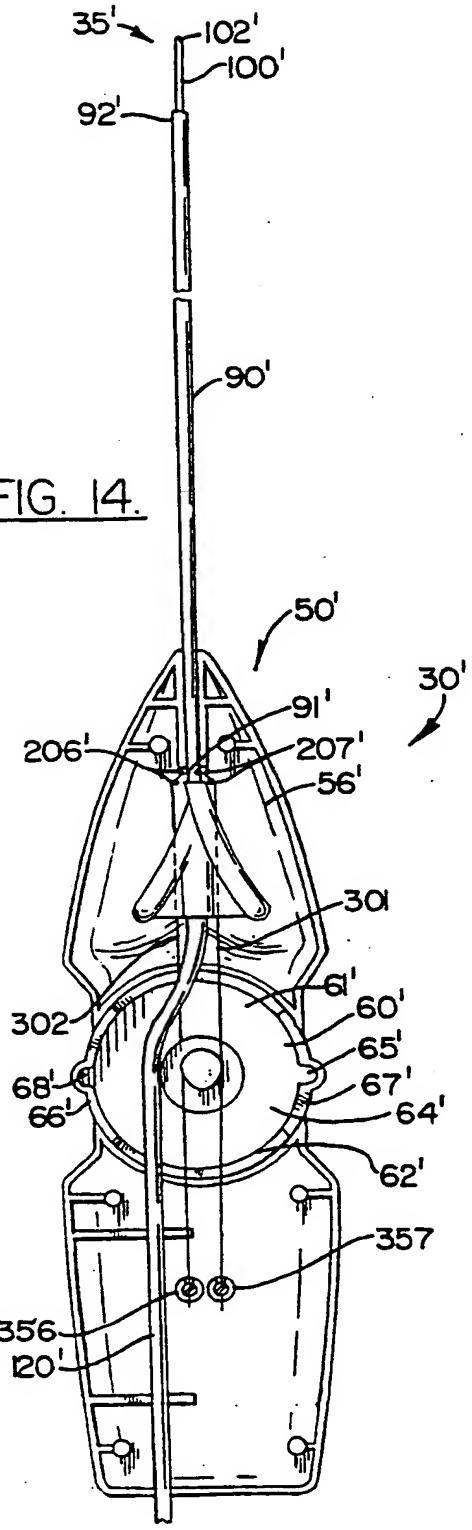
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FIG. 14.

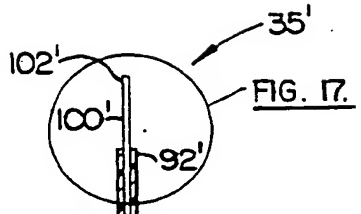

FIG. 17.

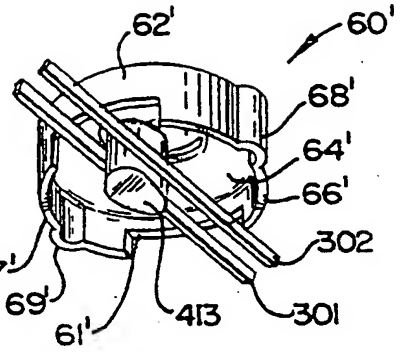

FIG. 16.

FIG. 15.

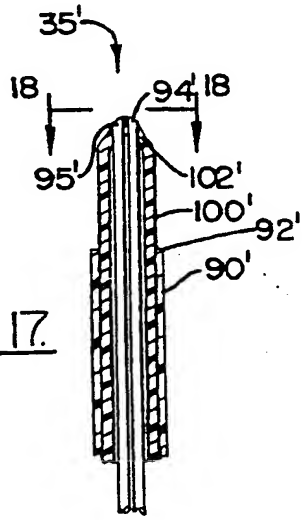

FIG. 17.

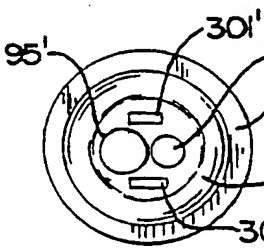

FIG. 18.

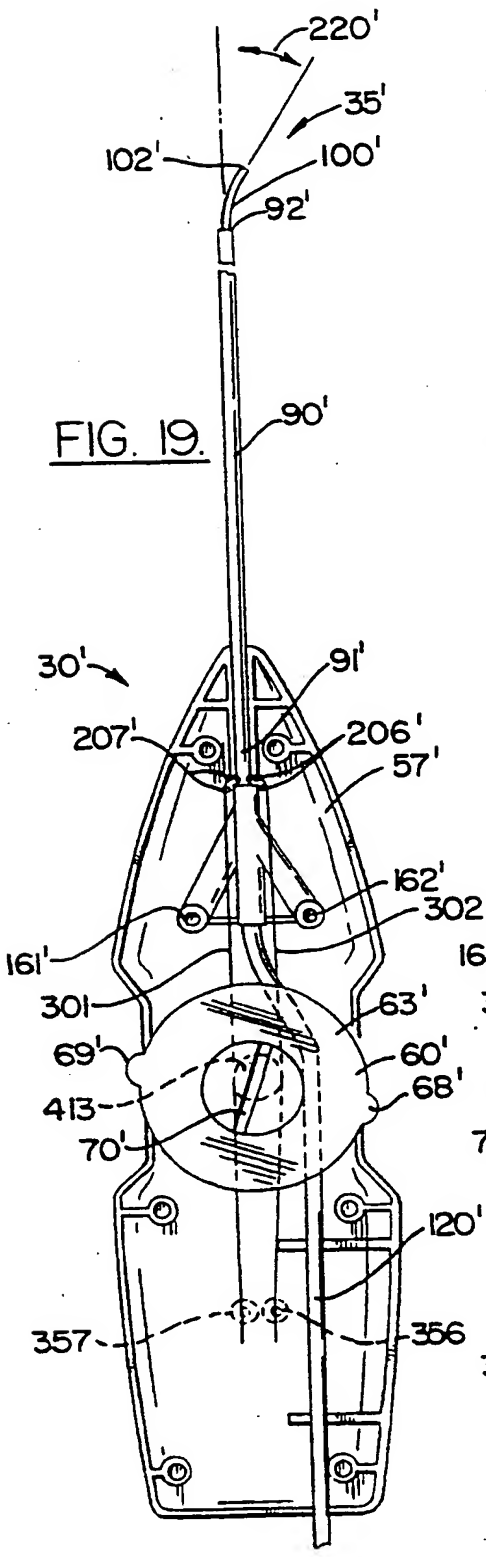
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FIG. 19.

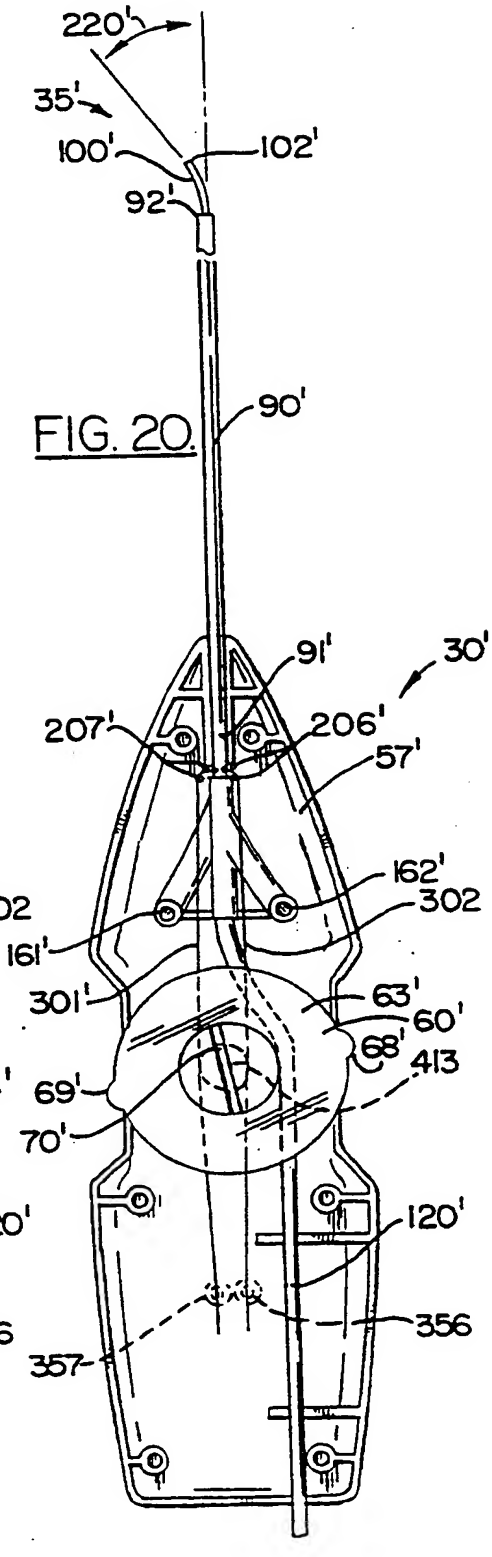
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FIG. 20.